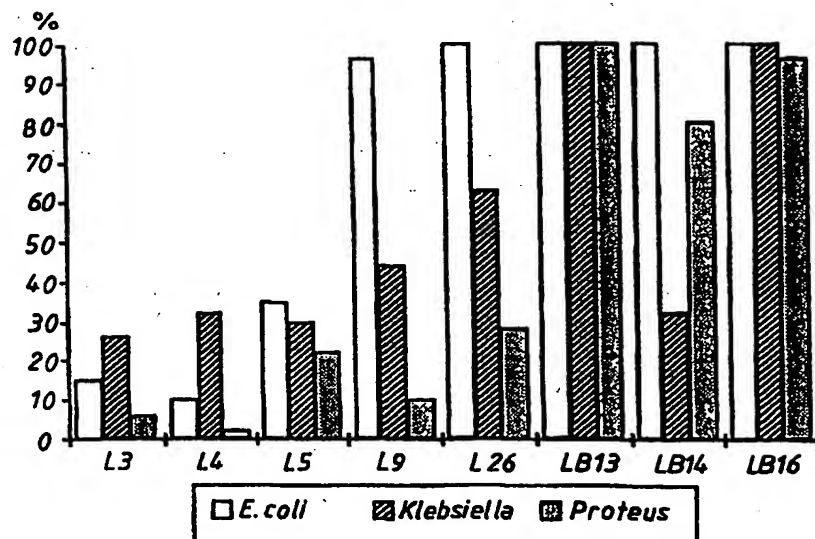




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(54) Title: **PRODUCT AND PREPARATION CONTAINING LACTIC ACID BACTERIA**

## (57) Abstract

Absorbent articles comprising lactic acid bacteria, and which articles can be stored for a long time under non-ideal conditions can be obtained by applying a suspension of lactic acid bacteria to an absorbent product, whereafter the absorbent product is dried to a moisture content of less than 10 %, preferably less than 5 %, and most preferably less than 1 %, calculated as percentage of weight of the absorbent core in the product. The absorbent product can be a diaper, sanitary napkin, panty liner, incontinence guard or like article. As already mentioned, it contains lactic acid bacteria and the article is intended to be carried in contact with the user's skin in the perineum area, wherein lactic acid bacteria are arranged to be transferred to the user's skin and, when applicable, to the mucus membrane in the perineum area, to form a microbiological barrier that impairs the conditions for spreading and establishment of undesirable stains of microorganisms in said perineum area.

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## PRODUCT AND PREPARATION CONTAINING LACTIC ACID BACTERIA

### FIELD OF INVENTION

- 5     The present invention relates to an absorbent article that contains lactic acid bacteria and that is intended to be brought into contact with a user's skin in the perineum.

### BACKGROUND OF THE INVENTION

- 10    Infections in the urogenital region is a problem that affects many individuals. In and around the anus, there are many different kinds of microorganisms as well as a large amount of these microorganisms. It is known that one reason for many infections in the urogenital region is that microorganisms from a person's own intestinal flora spread from the anus to urogenital organs over perineum and there cause infection.

15

- Normally, an ecological balance prevails between different microorganisms on skin and mucus membrane, and the normal microbiological flora is highly significant in preventing the establishment of undesirable microorganisms. Lactic acid bacteria, *inter alia*, play an active role in this respect. However, situations are found where this natural defence system is inadequate and is disturbed in a way that enables potentially pathogenic microorganisms to become established and give rise to infection, for instance in conjunction with medication, poor hygiene, skin changes and changes in mucus membranes.

20

- 25    Microorganisms that can be associated with the occurrence of these problems are, e.g., microorganisms from the genera *Escherichia*, *Enterococcus*, *Proteus*, *Klebsiella*, *Streptococcus*, *Gardnerella* and *Candida*.

- With regard to the danger of contracting infections in the urogenital region, old and young women are more at risk than men, due to the short distance from the anus to the urethra orifice and vagina.
- 30

Groups that are even more at risk in this respect are young girls who do not yet have a developed flora of lactic acid bacteria in the urogenital region, and older women who no longer have a developed flora of this nature.

5

Another risk group are individuals who have been treated with antibiotics against some other type of infection, resulting in a change in their general, natural microbiological flora and then also in the urogenital region.

- 10 A closely related problem resides in vaginal colonisation from the anus of, e.g., streptococci, etc. A large percentage of adult women (~30%) carry group B streptococci vaginally. Pregnant women from this group are a particular risk group, since the foetus or the newly born child can be contaminated and develop a serious infection.
- 15 A closely related problem is bacterial vaginosis. A large proportion of adult women (~10%) suffer from this. Pregnant women that have such problems constitute a risk group, since the condition can lead to a premature birth which constitutes a serious risk to the child's health.
- 20 Recurrent urinary tract infections are general in the case of many individuals, and the occurrence of such infections can lead to complications in the form of kidney damage, for instance, when relevant treatment is not available.
- 25 A natural part of the prophylaxis against infections in the urogenital region is enhanced personal hygiene. However, it can be unsuitable to wash genitals and lower abdomen with an excessively strong soap and bactericidal substances, and consequently it may be difficult for an individual to reduce the risk of infection to a sufficient level with the aid of conventional means.

Traditionally, the aforesaid problems are addressed by treating an infection with conventional antibiotics. However, frequent treatment with antibiotics leads to the development of resistant bacteria strains, which can make continued treatment of new infections very difficult. A further problem with antibiotic treatment is that many individuals are hypersensitive to antibiotics. Yet another problem with antibiotic treatment is that the microbiological flora in and around the anus is complex and relatively undefined. It is therefore difficult to propose a prophylactic treatment for reducing the risk of the occurrence of infections that can be caused by microorganisms from the intestines.

Hitherto, the only available method for reducing the risk of infection in the urogenital region has been treatment with antibiotics. However, since the use of antibiotics for a prophylactic purpose is unsuitable for several reasons, there is a serious need for an alternative solution to the problem by generating and maintaining a desired microbiological flora in the urogenital region.

## DESCRIPTION OF THE BACKGROUND ART

As earlier mentioned, a traditional method of dealing with the aforesaid problems is to treat the patient with conventional antibiotics. Various alternative methods of dealing with the aforescribed problems have been proposed. The use of bacteria as so-called probiotics as an alternative to antibiotics is part of this new methodology.

It is known that certain lactic acid bacteria can have an inhibiting effect on other microorganisms. Application of such lactic acid bacteria has been found to prevent the occurrence of infections on both skin and mucus membrane.

Medical use of selected strains of lactobacteria is described in Canadian Patent Specification CA 1298556 (Bruce, Reid), where, among other things, whole cells or fragments of cells of *Lactobacillus* are used to treat or to prevent the occurrence of urinal tract infections and intestinal infections.

International Patent Application WO 93/09793 (Reid) describes the use of lactobacteria and skim milk preparations to prevent the occurrence of urogenital infections.

- 5 Both CA 1298556 (Bruce, Reid) and WO 93/09793 (Reid) describe the ability of the microorganisms to fasten to the mucus membrane walls, e.g. to the uroepithelium cells or vaginal epithelium cells as an important component for the function of the treatment. However, neither CA 1298556 (Bruce, Reid) nor WO 93/09793 (Reid) describes how the substance concerned shall be applied to the user.

10

International Patent Application WO 92/13577 (Kvanta) teaches a tampon or sanitary napkin that has been impregnated with a culture of lactic acid producing bacteria, preferably of the genus *Pediococcus*, that has been isolated from healthy individuals. The tampon or sanitary napkin is intended for prophylactic treatment of urogenital infections.

15

WO 92/13577 (Kvanta) teaches that applied microorganisms of *Lactobacillus* are attenuated when technically handled, and the method described relates to treatment and prophylaxis around the actual urethra orifice.

- 20 The above cited documents are all solely directed to administration of lactic acid bacteria to the skin. However, none of the documents discloses anything about providing absorbent articles comprising lactic acid bacteria, which articles can be stored for a long time and still contain a sufficient amount of viable and transferable bacteria. It is absolutely necessary that consumer products such as absorbent articles can be stored for a
- 25 long time and under non-ideal conditions without risking that the quality of the articles is impaired. Consequently, there is a need for absorbent articles which articles are specially adopted for long-time storage under unfavourable conditions.

## SUMMARY OF THE INVENTION

It has now turned out that the above mentioned problems can be overcome, and a high quality can be ensured, by applying a suspension of lactic acid bacteria to an absorbent product, whereafter the absorbent product is dried to a moisture content of less than 10 %, preferably less than 5 %, and most preferably less than 1 %, calculated as percentage of weight of the absorbent core in the product. The absorbent product can be a diaper, sanitary napkin, panty liner, incontinence guard or like article. As already mentioned, it contains lactic acid bacteria and the article is intended to be carried in contact with the user's skin in the perineum area, wherein lactic acid bacteria are arranged to be transferred to the user's skin and, when applicable, to the mucus membrane in the perineum area, to form a microbiological barrier that impairs the conditions for spreading and establishment of undesirable stains of microorganisms in said perineum area.

## BRIEF DESCRIPTION OF THE DRAWINGS

The invention will now be described in greater depth with reference to the accompanying drawings.

Fig. 1 shows the results obtained with interference tests between selected lactic acid bacteria and undesirable microorganisms.

Fig. 2 illustrates schematically the construction of an inventive test product in the form of an insert.

## DETAILED DESCRIPTION OF THE INVENTION

Thus, an inventive absorbent article is intended to transfer lactic acid bacteria to the wearer's perineum and thereby produce a microbiological flora that impairs in the perineum the living conditions for undesirable strains of microorganisms. Undesirable

microorganisms are therewith prevented from spreading from the wearer's anus to the urogenital organs.

5 The lactic acid bacteria, or a preparation that contains lactic acid bacteria, is applied to an absorbent article such as a diaper, sanitary napkin, panty liner, incontinence guard and a like article.

10 Generally, the lactic acid bacteria are applied to the article by adding a suspension of said bacteria to the surface of the article that is intended to face the wearer. Preferably, this suspension contains skim milk. It is advantageous that the suspension is concentrated in order to reduce the total volume of the suspension, but on the other hand a highly concentrated suspension may lead to clogging problems in pipes and nozzles. A suitable concentration is within the range from  $1 \times 10^9$  to  $1 \times 10^{12}$  cfu/ml (colony-forming units per ml), and preferably within the range from  $1 \times 10^{10}$  to  $1 \times 10^{11}$  cfu/ml. This suspension  
15 can be added by spraying or pouring it onto the article. The aqueous part of the suspension is immediately absorbed into absorbing layers in the lower part of the article leaving the bacteria in the upper part of the article that is closest to the wearer in a substantially dry state. Despite this absorption, it has turned out to be essential to carry out a drying step in order to ensure that the moisture content of the finished article is less  
20 than 10 %, preferably less than 5 %, and most preferably less than 1 %, calculated as percentage of the weight of the absorbent core in the product.

The lactic acid bacteria will preferably have an inhibiting effect on the growth of undesirable microorganisms in the perineum.

25

Lactic acid bacteria that are suitable for use in accordance with the invention include one or more strains of the genera *Lactobacillus*, *Lactococcus* or *Pediococcus*. However, the lactic acid bacteria will preferably consist of one or more strains from the *Lactobacillus* genus.

30

The lactic acid bacteria can also be combined with other components, such as a pH-lowering substance or an auxiliary substance that will facilitate survival of the lactic acid bacteria. Powdered skimmed milk is one example of such an auxiliary substance.

- 5 An inventive absorbent article can be combined advantageously with the local administration of lactic acid bacteria in the vagina with the aid of a capsule, vagitorium or some like means. The inventive substance can also be used advantageously in direct conjunction with antibiotic treatment, for instance the treatment of a urogenital infection.
- 10 The invention can be applied with all types of absorbent articles that are intended to be worn in contact with the user's perineum. The lactic acid bacteria may therewith be included as a component in the absorbent body of the absorbent article, or applied in or on the liquid-permeable casing sheet of the article, or in or on a liquid transport layer between the liquid-permeable casing sheet and the absorbent body, or may be applied on
- 15 a separate carrier, such as a tissue layer or the like. The absorbent article may be a diaper, a sanitary napkin, an incontinence guard, or a panty liner. Such articles normally include an absorbent body or pad enclosed in a casing, wherein the casing suitably includes a liquid-permeable outer sheet over the surface that is intended to lie proximal to the wearer in use. An advantage is afforded when a liquid barrier layer, for instance in the
- 20 form of plastic film, is arranged adjacent the opposite surface which lies distal from the wearer in use.

When the lactic acid bacteria are disposed inwardly of the article casing, it is essential with respect to the invention that the bacteria are able to pass through the casing at that

25 surface of the article which is intended to lie against the wearer's skin in the perineum.

It has been found to be advantageous when the number of lactic acid bacteria in the absorbent article is between  $10^4$  cfu and  $10^{11}$  cfu, and preferably between  $10^6$  cfu and  $10^{10}$  cfu.

Alternatively, the absorbent article may have the form of an insert that includes means for its attachment to the liquid-permeable outer sheet of a conventional absorbent article. One advantage with the use of such an insert is that it avoids the need to produce products provided with lactic acid bacteria in a large number of different sizes and models.

5

As already mentioned, the object of the present invention is to provide an absorbent article of the aforementioned kind that will reduce spreading of bacteria from the anus to the urogenital organs with the aid of microbiological antagonism. This object has been achieved in accordance with the invention with an absorbent article that includes lactic acid bacteria. The absorbent article is intended to be used regularly and in contact with the wearer's skin in the perineum area. By regular use may, in this case, mean daily use or almost daily use of the inventive article. The lactic acid bacteria are therewith applied to the user's perineum area so as to produce and maintain in this area a microbiological flora that impairs the living conditions for undesirable microorganisms in said perineum area, and therewith prevent spreading of these microorganisms from the anus to the urogenital organs.

10  
15

Examples of species that are associated with urogenital infections are *Escherichia coli*, *Enterobacter*, *Klebsiella*, *Pseudomonas*, *Proteus*, *Staphylococcus saprophyticus*, *Staphylococcus epidermidis*, group B streptococci, Enterococci, *Candida* sp., *Chlamydia* sp., *Gardnerella vaginalis*, *Mobiluncus* and *Bacteroides* sp.

20

As before mentioned, the invention is based on microbiological antagonism. Microbiological antagonism implies that one microorganism or combinations of microorganisms will inhibit other microorganisms. An antagonistic strain shall exhibit growth inhibiting effects with conventional interference techniques on several of the aforesaid undesirable microorganisms. Other important requirements of a suitable antagonistic microorganism is its ability to survive during storage and its growth ability or ability to maintain its activity in a product during use.

25

30

Antagonistic microorganisms may be naturally occurring organisms that are non-toxic and that do not exert any negative biological effect on human beings, in the form of infection or skin changes. However, antagonistic microorganisms can also be produced by biotechnical processes.

5

Certain strains of lactic acid bacteria have a powerful inhibiting effect on undesirable bacteria strains in the user's perineum. This inhibitory effect has its foundation in the fact that lactic acid bacteria possess a number of antagonistic properties that act through different mechanisms, such as by lowering pH, e.g. by producing lactic acid, competition  
10 for available nutrients, reduction of the redox-potential, production of hydrogen peroxide, production of specific inhibiting substances or components, such as enzymes, toxins or bacteriocines and competition for available binding sites. The antagonistic effect can be elevated still further in some instances, by adding an additional pH-lowering substance.

15 The growth of undesirable microorganisms present in the perineum of the user can be inhibited by adding to the inventive product lactic acid bacteria that exhibit antagonistic properties against said undesirable microorganisms. At least some microorganisms of undesired species can also be killed in this way. The microorganisms added to the product must be added in such quantities and have such activities as to achieve the effect  
20 desired. This effect is normally achieved when the number of antagonistic microorganisms per product is greater than  $10^6$  cfu, preferably  $10^8$  cfu and more preferably  $10^9$  cfu.

One advantage afforded by the use of antagonistic microorganisms is that one avoids an  
25 undesired selection pressure on the microenvironment, such as favouring of potentially pathogenic microorganisms and therewith the risk of developing pathogenic strains that are resistant to antibiotics and chemopharmaceuticals. Since the antimicrobial system is based on a natural biological process, the risk of ecological and toxic environmental disturbances is reduced.

30

The inventive product can include a carrier in the form of, e.g., a typical panty liner with or without a liquid-impervious backing sheet and including an absorbent layer which contains 100-200 g/m<sup>2</sup> cellulose pulp mixed with 0-10% superabsorbent powder. That side of the product which is intended to lie proximal to the wearer in use includes lactic acid bacteria in a concentration that will preferably be in the order of 10<sup>4</sup>-10<sup>11</sup>, preferably 10<sup>6</sup>-10<sup>10</sup> cfu per product. An inventive product will preferably include a suitable substance that will assist in the survival of the microorganisms. One such aid may, e.g., be powdered skim milk. Regardless of the general form of the product, an inventive product may also include a suitable pH-lowering substance for further enhancing the antagonistic effect.

## EXAMPLES

The following examples are intended to further illustrate the effect of an inventive product.

### Example 1

Bacterial antagonism was studied with the aid of tests carried out in accordance with the agar overlay method. The method is based on the diffusion of the growth inhibiting substance produced by the lactic acid bacteria through an agar layer and their inhibition of the growth of the test organisms.

Lactic acid bacteria, three strains of *Lactobacillus* designated LB13, LB14 and LB16 respectively, and five strains of *Lactococcus* designated L3, L4, L5, L9 and L26 respectively, were cultivated to an overnight culture in nutrient broth from Merck. *Lactococcus* were cultivated in M17 and *Lactobacillus* in MRS. Agar (2%) of M17 and MRS (25 ml) respectively was mixed with 1.0 ml of respective bacteria and moulded in a Petri dish. The agar plates were incubated overnight at 37°C. The plates with MRS were incubated in a CO<sub>2</sub> atmosphere. Reference plates were prepared in a corresponding

manner, but without lactic acid bacteria. A fresh layer containing 25 ml agar was cast on top of the existing layer in the Petri dishes and allowed to solidify.

5 The test organisms in the form of gram-negative bacteria of respective *Escherichia coli*, *Klebsiella* spp and *Proteus* spp and 100, 91 and 50 strains respectively were cultivated in a broth, and a dilution corresponding to  $10^7$  cfu/ml was prepared in Bertani trays. The test bacteria were then stamped on the new agar layer with the aid of a Steers Steel Pin Replicator (Steers E et al, J. Antibiot Chemother (1979,9,307). The plates were incubated at 37°C for twenty-four hours. Subsequent to incubation, the plates were read and  
10 compared with the reference plates. When reading the plates, "growth", "inhibition" or "zero growth" were registered for respective test organisms. The pH of all agar layers was measured, and those plates with a pH below 5.0 were re-tested with pH-adjusted agar, i.e. with agar to which a small quantity of glucose was added to counteract pH reduction. The percentile proportion of the total number of test organisms that had been inhibited or gave  
15 zero growth was calculated.

The diagram in Fig. 1 shows the percentage of the different strains of *Escherichia coli*, *Klebsiella* and *Proteus* that were inhibited by the presence of the selected strains of genera *Lactobacillus* and *Lactococcus*. It is evident that the *Lactobacillus* strains LB13  
20 and LB16 have an inhibitory effect on practically all pathogenic strains. The *Lactobacillus* strain designated LB14 inhibited the growth of all *E.coli* strains, about 80% of the *Proteus* strains and slightly more than 30% of the *Klebsiella* strains. All of the *Lactococci* and *Lactobacilli* used had a growth inhibiting effect on some of the pathogenic strains. Of the *Lactococci* strains, inhibition of the highest percentage of  
25 pathogens was obtained with L26 and L9, both of which had an inhibitory effect on practically all *E. coli* strains and on a large percentage of the *Klebsiella* strains.

Example 2

The following tests were carried out with the intention of studying the transfer of lactic acid bacteria to the perineum of persons wearing panty liners. All test persons were females between 3-60 years of age. In some cases, the test was carried out between the menstruation periods of the test persons concerned. Test products were produced from conventional panty liners that included a liquid-permeable casing sheet, a liquid-impermeable back sheet, and an absorbent layer of chemical cellulose pulp, 100-200 g/m<sup>2</sup>, sandwiched therebetween. A suspension of selected lactic acid bacteria was sprayed on the absorbent side of the test products, in a concentration of 10<sup>9</sup> cfu per product.

The presence of lactic acid bacteria in the perineum of the test persons was determined with the aid of a so-called swab test. In this case, bacteria were collected by dipping a sterile stick provided with a cotton-wool top into a sterile saline solution and stroking the top of the stick over a defined area of the skin. The presence of lactic acid bacteria in the perineum of twenty test persons was determined, measured, in this way, to obtain a so-called 0-sample (background sample). The test persons then wore the panty liner for five hours over a morning period. The panty liners were then removed and the presence of lactic acid bacteria again measured, immediately after removing the panty liners. This test was designated Sample 1. A further test, designated Sample 2, was run after a further four-five hours. The type of lactic acid bacteria was identified on each sampling occasion, in order to ascertain that none of the test persons was a natural carrier of the selected type of lactic acid bacteria added to the test products. The identification method used was API (API-system, La Balme les Grottes, 38390 Montalieu, Vercieu, France).

The results obtained with these measuring processes are defined in Table 1.

Table 1

Presence of LAB\* in the Perineum (cfu)

TP	Flora	0-sample	Sample 1	Sample 2

	1	Added LAB	0	0	0
		Own LAB	0	0	0
5	2	Added LAB	0	$4.0 \times 10^1$	0
		Own LAB	0	0	0
	3	Added LAB	0	$7.2 \times 10^3$	$1.6 \times 10^2$
		Own LAB	0	0	0
10	4	Added LAB	0	0	0
		Own LAB	0	0	0
	5	Added LAB	0	$1.1 \times 10^2$	$5.0 \times 10^1$
		Own LAB	0	0	0
15	6	Added LAB	0	$5.0 \times 10^1$	$3.0 \times 10^1$
		Own LAB	+	+	0
	7	Added LAB	0	$3.2 \times 10^2$	$1.3 \times 10^3$
		Own LAB	+	+	+
20	8	Added LAB	0	$2.7 \times 10^3$	$6.0 \times 10^2$
		Own LAB	0	0	0
	9	Added LAB	0	$3.2 \times 10^3$	$1.0 \times 10^1$
		Own LAB	+	0	+
	10	Added LAB	0	$7.6 \times 10^2$	$7.0 \times 10^1$
		Own LAB	+	+	+
30	11	Added LAB	0	$8.4 \times 10^3$	$7.0 \times 10^1$
		Own LAB	+	+	+
	12	Added LAB	0	$3.5 \times 10^3$	$8.0 \times 10^1$
		Own LAB	0	0	0
35					

	13	Added LAB	0	$2.4 \times 10^2$	$3.0 \times 10^2$
		Own LAB	+	+	+
5	14	Added LAB	0	0	0
		Own LAB	+	+	+
	15	Added LAB	0	$2.1 \times 10^2$	$8.0 \times 10^1$
		Own LAB	+	+	+
10	16	Added LAB	0	$1.6 \times 10^4$	$4.0 \times 10^3$
		Own LAB	0	0	0
15	17	Added LAB	0	$6.0 \times 10^2$	$1.5 \times 10^2$
		Own LAB	+	+	+
	18	Added LAB	0	$9.3 \times 10^2$	$1.0 \times 10^1$
		Own LAB	0	0	0
20	19	Added LAB	0	$4.0 \times 10^1$	$1.0 \times 10^1$
		Own LAB	0	0	0
	20	Added LAB	0	$7.2 \times 10^3$	$7.0 \times 10^1$
		Own LAB	0	0	0
25		Added LAB	0		
		Own LAB	0		
Number of TP with added LAB			0	17	16

\*LAB = lactic acid bacteria

30 0 = no lactic acid bacteria were found on the test persons

+ = presence of own LAB on the test persons

As evident from Table 1, the selected lactic acid bacteria added to the test products were activated when the test products were worn by the test persons, and that the selected

lactic acid bacteria were transferred to the perineum area of said persons and found to be present in said area even for a relatively long period of time after having removed the test products.

### 5 Example 3

10 A clinical study was carried out with the aim of illustrating the effect of adding lactic acid bacteria to the uro-perineal flora of children suffering from myelomeningocele. The study was blind, randomised and with cross-over design. Twenty-three children aged from two to seventeen participated in the study. All children were diaper wearers. Test products in the form of inserts with and without lactic acid bacteria were placed nearest the skin in the standard diaper.

15 The construction of the insert 1 used is shown in Fig. 2. Arranged uppermost on the insert 1, i.e. nearest the wearer's skin, is a liquid-permeable casing sheet 2 made of nonwoven material. A thin tissue layer 3 is disposed immediately adjacent to and inwardly of the casing sheet 2. The insert 1 also includes an absorbent pad 4 consisting of a mixture of cellulose fluff pulp and superabsorbent material. Placed on the surface of the absorbent pad 4 proximal to the tissue layer 3 is a layer of freeze-dried milk powder 5 with or  
20 without an admixture of selected, freeze-dried lactic acid bacteria in a concentration of  $10^9$  cfu per insert. The tissue layer 3, the absorbent pad 4 and the powdered milk 5 were enclosed between the liquid-permeable casing sheet 2 and a similar liquid-permeable backing sheet 6 of nonwoven material.

25 Two glue strings 7 were provided on the bottom surface 6 intended to lie proximal to the diaper in use, to enable the insert 1 to be fastened to the diapers worn by the test children. The glue strings 7 were protected by release paper 8, prior to placing the insert 1 in respective diapers.

30 The absorbent pad 4 was formed as an absorbent layer of  $150 \text{ g/m}^2$  chemithermomechanical pulp admixed with 10% superabsorbent powder. The freeze-

dried milk powder, in the present case admixed with freeze-dried lactic acid bacteria, was sprinkled on the surface of the tissue layer 3 facing the absorbent pad 4. The tissue layer 3 had a weight per unit area of about 20 g/m<sup>2</sup> and was placed on top of the milk powder. The casing sheet 2 and the backing sheet 6 consisted of a nonwoven material having a weight per unit area of about 17 g/m<sup>2</sup> and were laminated in both sides by the absorbent unit 3-5. The thus produced insert 1 had an hourglass configuration with a largest width of about 9 cm, a smallest width of about 6.5 cm, and a length of about 24 cm.

The tests were continued over periods of 6 + 6 weeks with an intermediate period of three weeks. A urine culture was made prior to and during respective test periods (at two-week intervals) and a quantitative determination was made from the perineum and the urethra orifice. The number of bacteria obtained were transferred to a measurement scale between 0 and 5, where 0 denotes cfu <10<sup>2</sup>, 1 denotes cfu between 10<sup>2</sup> and 10<sup>3</sup>, and so on.

The results obtained are set forth in Table 2.

Table 2		Insert without LAB*		Insert with LAB*		Significance
Bacteria group	Local	M	SD	M	SD	
Potential	Perineum	1.93	0.84	1.52	0.89	Yes
Urinal	Urethra	1.62	1.12	1.29	0.95	No
Tract	Urine	1.93	1.72	1.43	1.39	Yes
Pathogens						

\*LAB = lactic acid bacteria

M = mean value

SD = standard deviation

It is evident from Table 2 that the insert containing selected lactic acid bacteria provides a statistically significant ( $p < 0.05$ ) reduction in the number of potential urinal tract pathogens (PUP) in the perineum and in the urine.

Example 4

The following tests were carried out with the intention of studying the survival of lactic acid bacteria in absorbent articles according to the invention. Test products were produced from conventional panty liners that included a liquid-permeable casing sheet, a liquid-impermeable back sheet, and an absorbent layer of chemical cellulose pulp, 100 - 200 g/m<sup>2</sup>, sandwiched therebetween. About 150 µl of a suspension of selected lactic acid bacteria in saline skim milk sprayed on the absorbent side of the test products, in a concentration of about  $9.0 \times 10^7$  cfu per product. Some test products were dried to a moisture content of less than 10 % (wt.) before they were packed in plastic packages, whereas other products were packed without any preceding drying step. The amount of living lactic acid bacteria was determined after 14, 28, 40 and 53 days, respectively using standard methods. The results of these tests are disclosed in Table 3 below:

Table 3

Day	dried panty liner		panty liner that has not been dried	
	cfu	cfu	cfu	cfu
0	$9.0 \times 10^7$	$7.0 \times 10^7$	$9.0 \times 10^7$	$7.0 \times 10^7$
14	$7.5 \times 10^6$	$6.1 \times 10^6$	$3.6 \times 10^5$	$8.0 \times 10^5$
20 28	$7.2 \times 10^7$	$2.6 \times 10^7$	$2.1 \times 10^4$	$1.0 \times 10^3$
40	$8.9 \times 10^7$	$3.2 \times 10^7$	$1.4 \times 10^4$	$1.0 \times 10^3$
53	$7.0 \times 10^7$	$3.0 \times 10^7$	$1.1 \times 10^4$	$1.0 \times 10^3$

As is evident from table 3 above, the amount of viable lactic acid bacteria does not decrease during the test period. However, the amount of viable lactic acid bacteria decreases considerably if no drying step is carried out before packaging.

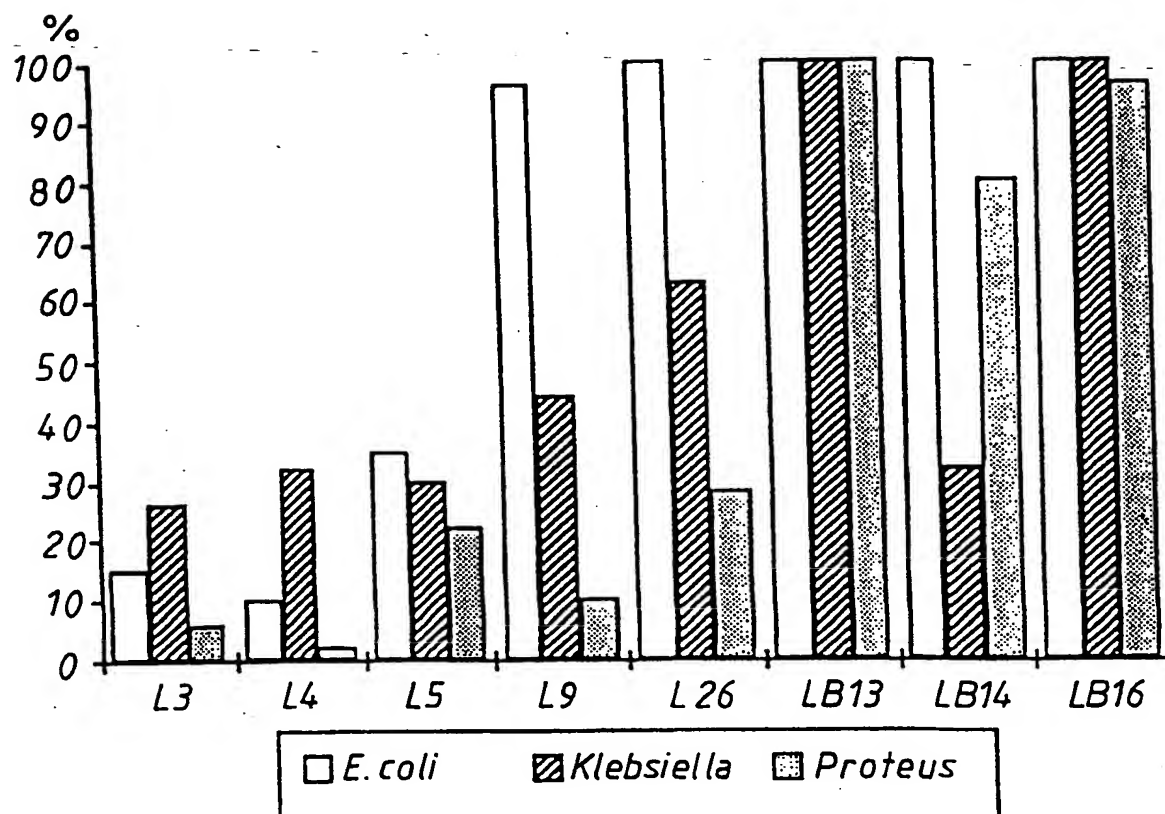
The invention shall not be considered to be restricted to the aforescribed examples, since it will be understood that a number of modifications and further embodiments are conceivable within the scope of the following Claims.

## CLAIMS

1. An absorbent product, such as a diaper, sanitary napkin, panty liner, incontinence guard, an insert or like article, which contains lactic acid bacteria and is  
5 intended to be carried in contact with the user's skin in the perineum area, wherein lactic acid bacteria are arranged to be transferred to the user's skin and, when applicable, to the mucus membrane in the perineum area, to form a microbiological barrier that impairs the conditions for spreading and establishment of undesirable stains of microorganisms in said perineum area, characterised in that said absorbent product has been produced by  
10 applying a suspension of said lactic acid bacteria whereafter the absorbent product is dried to a moisture content of less than 10 %, preferably less than 5 % and most preferably less than 1 %, calculated as percentage of the weight of the absorbent core in the product.
- 15 2. A product according to claim 1, wherein the lactic acid bacteria exhibit an inhibiting effect against undesirable microorganisms in the user's perineum.
3. A product according to any one of the preceding Claims, wherein the lactic acid bacteria include one or more strains from the genera Lactobacillus, Lactococcus or  
20 Pediococcus.
4. A product according to Claim 3, wherein the lactic acid bacteria consist of one or more strains from the genus Lactobacillus.
- 25 5. A product according to any one of the preceding Claims, wherein the product includes a pH-lowering substance.
6. A product according to any one of the preceding Claims, wherein the product includes an auxiliary substance for facilitating survival of the lactic acid bacteria.

7. A product according to Claim 6, wherein said auxiliary substance is powdered skim milk.
8. An absorbent article according anyone of Claims 1-7, wherein lactic acid  
5 bacteria are disposed in or on a liquid-permeable casing sheet (2) included in said article.
9. An absorbent article according to anyone of claims 1-7, wherein lactic acid bacteria are located directly below the liquid-permeable casing sheet (2).
- 10 10. An absorbent article according to Claim 8 or 9, wherein lactic acid bacteria are disposed in or on an absorbent pad (4) included in said article.
11. An absorbent article according to any one of Claims 1-10, wherein the article contains lactic acid bacteria in numbers from between  $10^4$  and  $10^{11}$  cfu, preferably  
15 between  $10^6$  and  $10^{10}$  cfu.

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FIG. 1

2/2

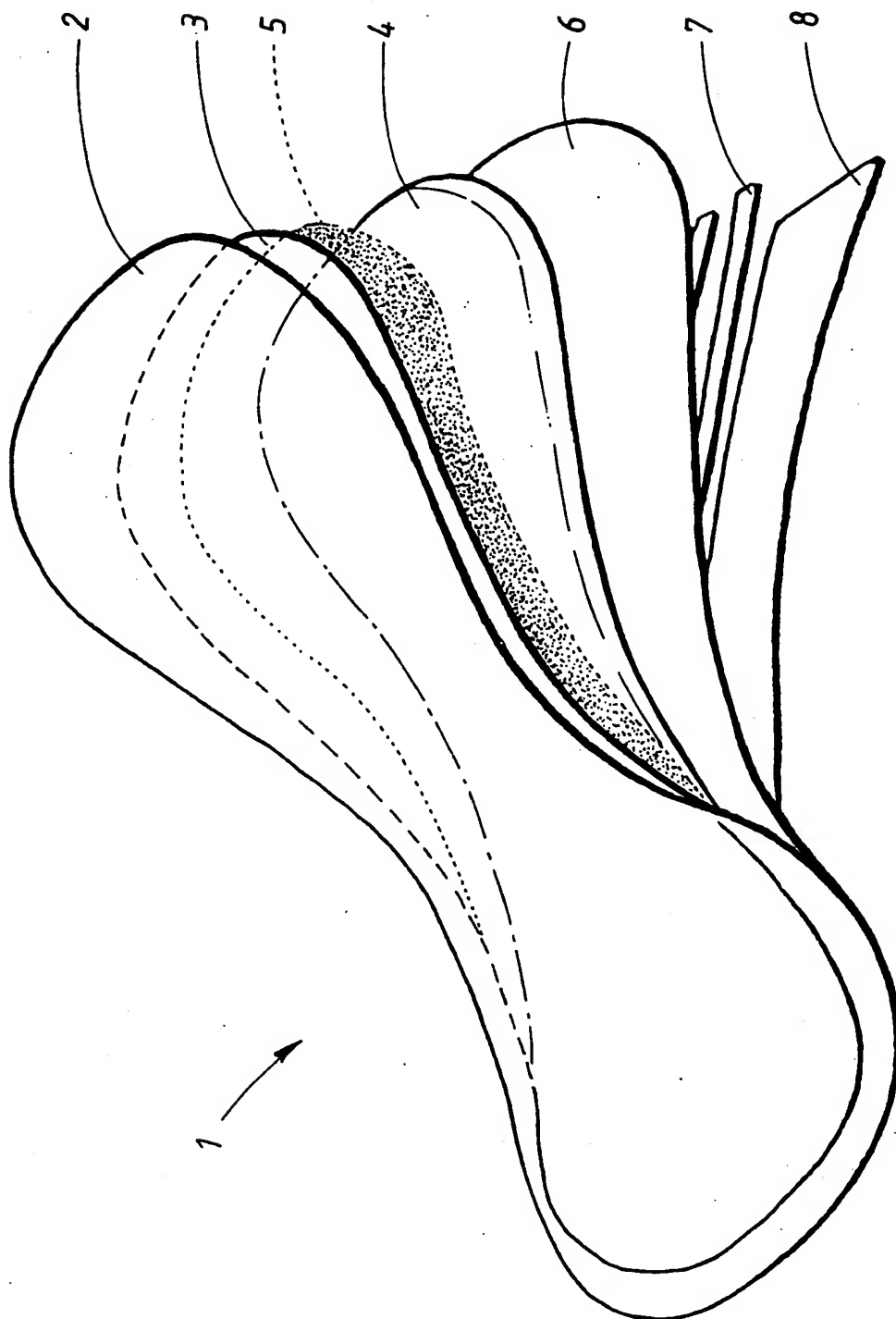


FIG. 2

# INTERNATIONAL SEARCH REPORT

1

International application No.

PCT/SE 98/01816

## A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61L 15/36, A61F 13/15

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61L, A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 9213577 A1 (LECUR DEVELOPMENT IN SWEDEN AKTIEBOLAG), 20 August 1992 (20.08.92)  --	1-11
A	WO 9309793 A1 (REID, GREGOR), 27 May 1993 (27.05.93)  --	1-11
A	WO 9702846 A1 (SCA MÖLNLYCKE AB), 30 January 1997 (30.01.97)  -----	1-11

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

\* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

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"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

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Date of the actual completion of the international search

26 January 1999

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**INTERNATIONAL SEARCH REPORT**  
Information on patent family members

21/12/98

International application No.

PCT/SE 98/01816

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